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United States Court of Appeals, Fourth Circuit.

GENBIOPRO, INC., Plaintiff – Appellant,
v.
Kristina RAYNES, in her official capacity as Prosecuting Attorney of Putnam County; Patrick Morrisey, in his official capacity as Attorney General of West Virginia, Defendants – Appellees,
and
Mark A. Sorsaia, in his official capacity as Prosecuting Attorney of Putnam County, Defendant.
Doctors for America; Economists; American College of Obstetricians and Gynecologists; Society for Maternal-Fetal Medicine; Society of Family Planning; State of North Carolina; Food and Drug Law and Health Law Scholars; City of Baltimore; Baltimore County, Maryland; Historians, Amici Supporting Appellant, Institute for Faith and Family; Family Research Council; Concerned Women for America; Life Legal Defense Foundation; American Center for Law and Justice; Advancing American Freedom, Inc., American Values; Americans United for Life; Anglicans for Life; Bob Carlstrom, President, Rebecca Webber, CEO, Association for Mature American Citizens; Center for Political Renewal; Center for Urban Renewal and Education (Cure); Christian Law Association; Christian Medical & Dental Associations; Eagle Forum; Family Council in Arkansas; Charlie Gerow; Global Liberty Alliance; International Conference of Evangelical Chaplain Endorsers; Tim Jones, Fmr. Speaker, Missouri House, Chairman, Missouri Center-Right Coalition; Louisiana Family Forum; Men and Women for Representative Democracy in America, Inc.; Men for Life; National Center for Public Policy Research; National Religious Broadcasters; New Jersey Family Foundation; New Jersey Family Policy Center; Pennsylvania Eagle Forum; Project 21 Black Leadership Network; Pro-Life Wisconsin; Rio Grande Foundation; Setting Things Right; 60 Plus Association; Students for Life of America; the Christian Law Association; the Family Foundation (Virginia); the Justice Foundation; Tradition, Family, Property, Inc.; Women for Democracy in America, Inc.; Wisconsin Family Action Institute; Young America's Foundation; Judicial Watch, Inc.; Arkansas and 22 Other States; Heartbeat International, Amici Supporting Appellees.

No. 23-2194
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Argued: October 29, 2024
|
Decided: July 15, 2025

Appeal from the United States District Court for the Southern District of West Virginia, at Huntington. Robert C. Chambers, District Judge. (3:23–cv–00058)

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Before WILKINSON and BENJAMIN, Circuit Judges, and Rossie D. ALSTON, Jr., United States District Judge for the Eastern District of Virginia, sitting by designation.

Opinion

Affirmed by published opinion. Judge Wilkinson wrote the opinion, in which Judge Alston joined. Judge Benjamin wrote an opinion concurring in part and dissenting in part.

WILKINSON, Circuit Judge:

***1** After the Supreme Court "return[ed] the issue of abortion to the people's elected representatives" in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215, 232, 142 S.Ct. 2228, 213 L.Ed.2d 545 (2022), West Virginia enacted a law prohibiting abortion in most circumstances. The question before us is whether certain federal standards regulating the distribution of the abortion drug mifepristone preempt the West Virginia law as it applies to medication abortions. The district court determined there was no preemption, and we now do the same.

For us to once again federalize the issue of abortion without a clear directive from Congress, right on the heels of *Dobbs*, would leave us one small step short of defiance. Appellant GenBioPro finds this clear directive in a maze of provisions in the Food and Drug Administration Amendments Act of 2007. It argues that these provisions vested the FDA with the exclusive authority to regulate access to mifepristone. We disagree. In our view, the Act leaves the states free to adopt or diverge from West Virginia's path. Because the Act falls well short of expressing a clear intention to displace the states' historic and sovereign right to protect the health and safety of their citizens, we affirm.

I.

A.

Mifepristone is the first drug in a two-drug medication abortion regimen. As with other drugs, mifepristone is subject to federal laws regulating drug safety and effectiveness. The cornerstone of the federal drug regulatory regime is the Federal Food, Drug, and Cosmetic Act (FDCA), which requires drug manufacturers to obtain Food and Drug Administration (FDA) approval before introducing new drugs to the market. Pub. L. No. 75-717, 52 Stat. 1040, 1052, 21 U.S.C. § 355(a).

In 2007, Congress enacted the Food and Drug Administration Amendments Act (FDAAA) to enhance the FDA's postmarket authority over high-risk drugs. Pub. L. No. 110-85, 121 Stat. 823, 823. Under the FDAAA, the FDA may require a drug's manufacturer to develop and implement a Risk Evaluation and Mitigation Strategy (REMS) when "necessary to ensure that the benefits of the drug outweigh the risks." 21 U.S.C. § 355-1(a)(1). A REMS may require the distribution of medication guides, package inserts, and other safety information to providers and patients. *Id.* § 355-1(e).

For especially risky drugs, a REMS may include

additional safety measures. For a drug "that would otherwise be unavailable" due to "its inherent toxicity or potential harmfulness," the FDA may require the REMS to "include such elements as are necessary to assure safe use." *Id.* § 355-1(f)(1). Examples of safe-use elements include requiring prescribers to receive specialized training, limiting dispensing to certain health care settings, or mandating protocols for patient monitoring. *Id.* § 355-1(f)(3). Safe-use elements must satisfy certain criteria. They must "be commensurate with the specific serious risk listed in the labeling of the drug," include "an explanation of how such elements will mitigate the observed safety risk," "not be unduly burdensome on patient access to the drug," conform with safe-use elements for drugs with similar risks, and be compatible with existing distribution systems. *Id.* § 355-1(f)(2).

***2** The FDA has subjected mifepristone to a REMS since 2011. Under the most recent REMS, mifepristone may only be prescribed and dispensed by specially certified providers and pharmacies. Certified providers must be able to assess the duration of pregnancy, identify ectopic pregnancies, and provide surgical intervention in the case of a medical emergency. They must also agree to review an agreement form with the patient and fully explain the risks of taking mifepristone to induce an abortion. Certified pharmacies must adhere to strict shipping and recordkeeping protocols. *See* U.S. Food & Drug Admin., Risk Evaluation and Mitigation Strategy (REMS): Single Shared System for Mifepristone 200 mg (2023).

B.

In June 2022, the Supreme Court held that "the authority to regulate abortion must be returned to the people and their elected representatives." *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 292, 142 S.Ct. 2228, 213 L.Ed.2d 545 (2022). Shortly after this decision, West Virginia enacted a law prohibiting abortion in most circumstances. *See* Unborn Child Protection Act, W. Va. Code § 16-2R. The law defines "abortion" as "the use of any instrument, medicine, drug, or any other substance or device with the intent to terminate the pregnancy of a patient known to be pregnant and with intent to cause the death and expulsion or removal of an embryo or a fetus." *Id.* § 16-2R-2. It then provides that an abortion may not be "performed," "induced," or "attempted" except in cases of nonviability, ectopic pregnancy, or medical emergency. *Id.* § 16-2R-3(a). This general prohibition does not apply in the early weeks of pregnancies resulting from sexual assault or incest. *Id.* § 16-2R-3(b)–(c).

Violations are punishable by civil and criminal sanctions. A "licensed medical professional" who "knowingly and willfully performs, induces, or attempts to perform or induce an abortion" in violation of the law "shall" have their license revoked. *Id.* § 16-2R-7. Any other person "who knowingly and willfully performs, induces, or attempts to perform or induce an abortion" commits a felony punishable by at least three but not more than ten years' imprisonment. *Id.* § 61-2-8(a)–(b). The statute does, however, make explicit that no pregnant woman who receives an unlawful abortion may be held criminally liable. *Id.* § 61-2-8(c) ("This section shall not be construed to subject any pregnant female upon whom an abortion is performed or induced or attempted to be performed or induced to a criminal penalty for any violation of this section as a principal, accessory, accomplice, conspirator, or aider and abettor.").

C.

GenBioPro manufactures generic mifepristone. In January 2023, the company filed a complaint in the U.S. District Court for the District of West Virginia asking the court to enjoin state officials from enforcing West Virginia's abortion law. GenBioPro argued that the law was preempted by the FDAAA. In its view, the FDAAA established a comprehensive scheme for regulating the narrow field of REMS drugs with safe-use elements that left no room for complementary state regulation. GenBioPro also argued that West Virginia's law frustrated the balance that the FDAAA struck between drug safety and patient access.

The district court rejected both preemption arguments. At the outset, the court recognized that "abortion is a matter of health and safety" and that "regulation of health and safety is a field that States have traditionally occupied." *GenBioPro, Inc. v. Sorsaia*, No. 23-0058, 2023 WL 5490179, at *5 (S.D. W. Va. Aug. 24, 2023). And since a presumption against preemption applies "[w]here Congress acts in a field traditionally occupied by the States," the district court determined "that Congress has not expressed an intent to occupy the field of drugs subject to a REMS in a manner which would preempt West Virginia's abortion restrictions." *Id.* at *10. Regarding the balance struck by the FDAAA, the court determined that the requirement that the FDA consider patient access "is plainly a limitation on the FDA's *own restrictions* on a drug, rather than a command that the FDA assure access for all patients." *Id.* at *6. The court concluded that West Virginia's law was "a restriction on the incidence of abortion, rather than a state directive in

direct conflict with the logistical REMS regulations." *Id.* at *8. Finding no preemption,[1] the district court granted West Virginia's motion to dismiss. GenBioPro timely appealed.

[1] The district court did find preemption with respect to a separate West Virginia law prohibiting the prescribing of mifepristone by telemedicine. *GenBioPro*, 2023 WL 5490179, at *10. That provision is not at issue in this appeal.

II.

***3** We first address whether GenBioPro has standing to sue. To establish standing, a plaintiff must show that it has a "personal stake" in the case. *Biden v. Nebraska*, 600 U.S. 477, 489, 143 S.Ct. 2355, 216 L.Ed.2d 1063 (2023). That means demonstrating "an injury in fact caused by the defendant and redressable by a court order." *United States v. Texas*, 599 U.S. 670, 676, 143 S.Ct. 1964, 216 L.Ed.2d 624 (2023). The causation and redressability requirements are "flip sides of the same coin." *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 380, 144 S.Ct. 1540, 219 L.Ed.2d 121 (2024) (quoting *Sprint Commc'ns Co. v. APCC Servs., Inc.*, 554 U.S. 269, 288, 128 S.Ct. 2531, 171 L.Ed.2d 424 (2008)). "If a defendant's action causes an injury, enjoining the action or awarding damages for the action will typically redress that injury." *Id.* at 381, 144 S.Ct. 1540.

As with any issue, "the procedural posture of the case dictates the plaintiff's burden as to standing." *Beck v. McDonald*, 848 F.3d 262, 270 (4th Cir. 2017). At the motion to dismiss stage, "the facts alleged in the complaint are taken as true" so long as "there is sufficient 'factual matter' to render them 'plausible.' " *Id.* (first quoting *Kerns v. United States*, 585 F.3d 187, 192 (4th Cir. 2009); then quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009)). Even "general factual allegations of injury resulting from the defendant's conduct may suffice" because at the pleading stage we "presume that general allegations embrace those specific facts that are necessary to support the claim." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992).

Given this standard, we have no trouble concluding that GenBioPro has adequately alleged standing at this stage. The complaint alleges that West Virginia's abortion law has "caused significant, ongoing economic injury to GenBioPro" by "severely constrict[ing] [its] pool of potential customers" in the state. J.A. 41. The Supreme Court's cases make clear that a plaintiff demonstrates standing when it challenges a law limiting its market. *Biden*, 600 U.S. at 490–91, 143 S.Ct. 2355; *see also Craig v. Boren*, 429 U.S. 190, 194, 97 S.Ct. 451, 50 L.Ed.2d 397 (1976) (law banning beer sales to men under twenty-one caused an "economic injury through the constriction of [the] buyers' market"). After all, "financial harm is a classic and paradigmatic form of injury in fact," *Air Evac EMS, Inc. v. Cheatham*, 910 F.3d 751, 760 (4th Cir. 2018) (quoting *Cottrell v. Alcon Lab'ys*, 874 F.3d 154, 163 (3d. Cir. 2017)), and a statute banning the use of a product plainly causes economic injury in the form of lost sales.

West Virginia does not dispute that a company has standing when it challenges a law limiting its market. Rather, it argues that the abortion law does not affect GenBioPro's market because the company has never sold mifepristone in West Virginia or taken the legal steps required to do so in the future, such as certifying providers to prescribe the drug. We find this argument unavailing. The thrust of the complaint is that the abortion law makes it "impossible for GenBioPro to promote and market its product in West Virginia as it does in other states." J.A. 41. It alleges that "healthcare providers in West Virginia *would* prescribe mifepristone to their patients and purchase that mifepristone from GenBioPro ... but do not because of the [b]an." *Id.* at 42 (emphasis added). Taking these allegations as true, it is more than plausible that GenBioPro would take the necessary steps to sell mifepristone in West Virginia were it not for the abortion law. That GenBioPro has not already certified providers to prescribe a drug they are currently prohibited from selling is unsurprising.[2]

[2] West Virginia also argues on appeal that GenBioPro lacks a cause of action. This argument is forfeited because it was not presented to the district court.

***4** With standing resolved, we now turn to the merits.

III.

A.

Over two centuries of experience have revealed the enduring wisdom of our republic's federalist design. The dynamic interplay between joint sovereigns has fostered "innovation and experimentation in government," "increase[d] opportunity for citizen involvement in democratic processes," and made government more

attuned to the "diverse needs of a heterogenous society." *Gregory v. Ashcroft*, 501 U.S. 452, 458, 111 S.Ct. 2395, 115 L.Ed.2d 410 (1991). With dual sovereignty, however, "follows the possibility that laws can be in conflict or at cross-purposes." *Arizona v. United States*, 567 U.S. 387, 398–99, 132 S.Ct. 2492, 183 L.Ed.2d 351 (2012). The Supremacy Clause addressed this problem by making federal law "the supreme Law of the Land." U.S. Const. art. VI, cl. 2. As a result, in our system federal statutes take precedence over conflicting state laws provided that Congress acted within its authority. *See Gregory*, 501 U.S. at 460, 111 S.Ct. 2395.

The Supreme Court has often "used different labels to describe the different ways in which federal statutes may displace state laws," making reference to "express," "field," and "conflict" preemption. *Va. Uranium, Inc. v. Warren*, 587 U.S. 761, 767, 139 S.Ct. 1894, 204 L.Ed.2d 377 (2019) (plurality opinion). But regardless of the label, "[p]re-emption fundamentally is a question of congressional intent." *English v. Gen. Elec. Co.*, 496 U.S. 72, 78–79, 110 S.Ct. 2270, 110 L.Ed.2d 65 (1990). Our task is therefore the same as in any other case involving statutory interpretation—we must discern Congress's intent by analyzing the statute's text.

As with any text, the words of a statute do not exist "in a contextual vacuum." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996). "Part of a fair reading of statutory text is recognizing that 'Congress legislates against the backdrop' of certain unexpressed presumptions." *Bond v. United States*, 572 U.S. 844, 857, 134 S.Ct. 2077, 189 L.Ed.2d 1 (2014) (*Bond II*) (quoting *EEOC v. Arabian Am. Oil Co.*, 499 U.S. 244, 248, 111 S.Ct. 1227, 113 L.Ed.2d 274 (1991)). To take two familiar examples, we routinely assume that Congress does not intend for statutes to apply retroactively or extraterritorially unless it clearly specifies otherwise. *See Landgraf v. USI Film Prods.*, 511 U.S. 244, 270, 114 S.Ct. 1483, 128 L.Ed.2d 229 (1994) (retroactivity); *Morrison v. Nat'l Australia Bank Ltd.*, 561 U.S. 247, 255, 130 S.Ct. 2869, 177 L.Ed.2d 535 (2010) (extraterritoriality). Our expectation of clarity in those contexts reflects the basic assumption that lawmakers do not usually "intrude on sensitive domains" with general language. *Spector v. Norwegian Cruise Line Ltd.*, 545 U.S. 119, 139, 125 S.Ct. 2169, 162 L.Ed.2d 97 (2005) (plurality opinion); *cf. Ala. Ass'n of Realtors v. HHS*, 594 U.S. 758, 764, 141 S.Ct. 2485, 210 L.Ed.2d 856 (2021) ("We expect Congress to speak clearly when authorizing an agency to exercise powers of 'vast economic and political significance.' " (quoting *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324, 134 S.Ct. 2427, 189 L.Ed.2d 372 (2014))).

One of those sensitive domains is the federal-state relationship. When reading statutes, we assume "Congress normally preserves 'the constitutional balance between the National Government and the States.' " *Bond II*, 572 U.S. at 862, 134 S.Ct. 2077 (quoting *Bond v. United States*, 564 U.S. 211, 222, 131 S.Ct. 2355, 180 L.Ed.2d 269 (2011)). For example, we presume that Congress does not intend to abrogate state sovereign immunity, impose duties on the states, or exercise its enforcement authority under the Fourteenth Amendment unless it clearly articulates an intent to do so. *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 243, 105 S.Ct. 3142, 87 L.Ed.2d 171 (1985) (state sovereign immunity); *Will v. Mich. Dep't of State Police*, 491 U.S. 58, 64, 109 S.Ct. 2304, 105 L.Ed.2d 45 (1989) (duties); *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 16–17, 101 S.Ct. 1531, 67 L.Ed.2d 694 (1981) (Fourteenth Amendment).

***5** The same principle applies when we consider preemption. It is well-established that, "[i]n areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention 'clear and manifest.' " *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449, 125 S.Ct. 1788, 161 L.Ed.2d 687 (2005) (quoting *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655, 115 S.Ct. 1671, 131 L.Ed.2d 695 (1995)). The need for clarity in statutory preemption is grounded in the rudiments of constitutional structure. "As every schoolchild learns, our Constitution establishes a system of dual sovereignty." *Gregory*, 501 U.S. at 457, 111 S.Ct. 2395. It vests limited powers in the national government while reserving a "residuary and inviolable sovereignty" to the states. The Federalist No. 39, at 245 (James Madison) (Clinton Rossiter ed., 1961). This constitutional structure is "a point of context that no reasonable interpreter could ignore." *Biden*, 600 U.S. at 516, 143 S.Ct. 2355 (Barrett, J., concurring). Given that the ability to override the historic police powers of the states "is an extraordinary power in a federalist system," the Supreme Court expects Congress to be clear when it wants to wield this authority. *Gregory*, 501 U.S. at 460, 111 S.Ct. 2395. Unless a statute reveals a clear and manifest intent to the contrary, we must presume Congress does not intend to upend the historic relationship of the federal and state governments.

In sum, the presumption against preemption embodies this simple thought. State statutes often address volatile subjects (here abortion), which in turn elicit strong objections among people of the utmost good faith. The corrective, however, may lie less with preempting the statute than by seeking its repeal or sanding off its rough

edges through the state's political process. Alteration and amendment are a more responsive and accountable path than having a distant sovereign knock the entire enactment out of the box. Congress of course can land that punch but, to repeat, Congress must be clear.

B.

Among the areas of traditional state authority to which the presumption against preemption applies is the "regulation of matters related to health and safety." *Hillsborough Cnty. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 715, 105 S.Ct. 2371, 85 L.Ed.2d 714 (1985). State legislators have long "exercised their police powers to protect the health and safety of their citizens" and "traditionally have had great latitude" to do so. *Medtronic*, 518 U.S. at 475, 116 S.Ct. 2240 (quoting *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756, 105 S.Ct. 2380, 85 L.Ed.2d 728 (1985)). Abortion does not lie beyond this basic state prerogative. As the Supreme Court recognized in *Dobbs*, states have regulated abortion since the earliest days of American law. *Dobbs* made this point one of particular emphasis. It drove the point home. All of the fifty-one state and territorial statutes meticulously analyzed in that decision prohibited the use of medicine or drugs to accomplish an abortion, just as the state law we deal with here does. *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 250, 302–30, 142 S.Ct. 2228, 213 L.Ed.2d 545 (appendices). The West Virginia law thus fits comfortably within a long history of state regulation of abortion.

Given the Supreme Court's emphasis on the historic ability of states to regulate the use of drugs or medicine to accomplish an abortion, it is clear that the presumption against preemption must apply here. On its face, the West Virginia law regulates the conduct of abortion. It was enacted for the express purpose of "protecting unborn lives" and establishes that "[a]n abortion may not be performed or induced or be attempted to be performed or induced" unless an exception applies. W. Va. Code. §§ 16-2R-1, 3(a). Because the states have long regulated abortion under their traditional authority over matters of health and safety, we must assume the FDAAA does not preempt West Virginia's law unless that intention is "clear and manifest." *Bates*, 544 U.S. at 449, 125 S.Ct. 1788 (quoting *N.Y. State Conf.*, 514 U.S. at 655, 115 S.Ct. 1671).

GenBioPro sees it differently. While it acknowledges that "health care in general is an area of traditional state regulation," it argues that West Virginia's abortion law departs from traditional exercises of the police power by restricting access to a drug subject to extensive federal regulation under the FDAAA. Opening Brief at 71. Because in its view the West Virginia law intrudes into a federal domain, it argues that the presumption is inapplicable.

***6** This view is inconsistent with established case law. It is true that the presumption against preemption "is not triggered when the State regulates in an area where there has been a history of significant federal presence." *United States v. Locke*, 529 U.S. 89, 108, 120 S.Ct. 1135, 146 L.Ed.2d 69 (2000). But this principle has been confined to situations where the state law *targets* a federal domain. In *Locke*, for example, the Supreme Court declined to apply the presumption to a state law regulating oil tankers in maritime commerce, an area historically dominated by federal regulation. *Id.* at 107, 120 S.Ct. 1135. Similarly, our cases have found the presumption inapplicable to state statutes criminalizing the circumvention of federal immigration law, *United States v. South Carolina*, 720 F.3d 518, 529 (4th Cir. 2013), and restricting the authority of national banks, *Epps v. JP Morgan Chase Bank*, 675 F.3d 315, 322 (4th Cir. 2012); *Nat'l City Bank of Ind. v. Turnbaugh*, 463 F.3d 325, 330 (4th Cir. 2006).

In each of these cases, the state law directly regulated an issue within a traditionally federal domain. Here, the object of West Virginia's law is abortion—an issue within the historical domain of the states. While it may affect a federally regulated drug, this effect is but incidental to the law's regulation of abortion. Accepting GenBioPro's argument would require extending these cases beyond situations where a state law targets a federal domain to those where it merely has some incidental effect on one.

We decline to take what by any measure would be a momentous step. Preemption in this instance would upend the federal-state balance by supplanting every state law tangentially touching the federal domain. Again, the Supreme Court insists that Congress speak clearly if it intends such a sweeping departure from our federalist framework. To allow Congress to preempt the core of state authority through implication or indirection is to subject dual sovereignty to the vagaries of law that the Supreme Court has roundly condemned in other fields. *See, e.g., West Virginia v. EPA*, 597 U.S. 697, 721, 142 S.Ct. 2587, 213 L.Ed.2d 896 (2022) (agency authority); *Landgraf*, 511 U.S. at 270, 114 S.Ct. 1483 (retroactivity); *Morrison*, 561 U.S. at 255, 130 S.Ct. 2869 (extraterritoriality); *In re Kan. Indians*, 72 U.S. (5 Wall.) 737, 760, 18 L.Ed. 667 (1866) (tribal sovereignty); *Murray v. Schooner Charming Betsy*, 6 U.S. (2 Cranch) 64, 118, 2 L.Ed. 208 (1804) (international law).

IV.

Having established that we must start with a presumption against preemption, we now consider whether the FDAAA demonstrates a clear intention on the part of Congress to displace West Virginia's abortion law.

A.

We begin by addressing GenBioPro's field preemption theory. GenBioPro argues that the FDAAA "occupied the field of regulating access to REMS drugs with safe-use elements." Opening Brief at 26. In its view, West Virginia's abortion law intrudes into this field by restricting access to mifepristone.

We disagree. West Virginia's abortion law and the FDAAA operate in different fields. West Virginia's law regulates the incidence of abortion. It determines whether an abortion may be performed at all, prohibiting the procedure in all but a few specific circumstances. In contrast, the FDAAA permits the FDA to regulate how mifepristone must be prescribed and dispensed *if and when* a medication abortion is performed. In other words, West Virginia's abortion law operates in a field upstream from the FDAAA. And a "state law regulating an upstream activity [like abortion] within the State's authority is not preempted simply because a downstream activity [like medication safety] falls within a federally occupied field." *Va. Uranium, Inc. v. Warren*, 587 U.S. 761, 790–91, 139 S.Ct. 1894, 204 L.Ed.2d 377 (2019) (Ginsburg, J., concurring in the judgment); *see also Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 467, 132 S.Ct. 965, 181 L.Ed.2d 950 (2012).

***7** And even were we to assume the state and federal laws regulate the same field, that field is not one that Congress has occupied. GenBioPro argues that the FDAAA "occupied the field of regulating access to REMS drugs with safe-use elements" by creating "a framework of regulation so pervasive" that there is "no room for the States to supplement it" and by addressing "a federal interest so dominant that the federal system [must] be assumed to preclude enforcement of state laws on the same subject." Opening Brief at 26 (quoting *Arizona v. United States*, 567 U.S. 387, 399, 132 S.Ct. 2492, 183 L.Ed.2d 351 (2012)).

There are two big problems with this argument. For one, defining the preempted field by restating the precise subject addressed by the FDAAA strikes us as tautological. The Supreme Court long ago rejected the notion that federal statutes automatically preempt state laws on the same topic. *See Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230–31, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947); *see also* Caleb Nelson, Statutory Interpretation 1120 (2d ed. 2024). Under modern preemption doctrine, preempted fields must be defined by asking "exactly what restrictions on state lawmaking power does the relevant federal statute imply?" Nelson, *supra*, at 1124.

A second problem with GenBioPro's theory is that the Supreme Court has consistently resisted inferring field preemption solely from "pervasive regulation" or the presence of a "dominant federal interest." *N.Y. State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 415, 93 S.Ct. 2507, 37 L.Ed.2d 688 (1973) (pervasiveness); *Hillsborough Cnty. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 719, 105 S.Ct. 2371, 85 L.Ed.2d 714 (1985) (federal interest). We do not dispute that the FDAAA subjects many drugs to a detailed regulatory framework. But modern issues "often by their very nature require intricate and complex responses from the Congress" even when it does not intend "its enactment as the exclusive means of meeting the problem." *Dublino*, 413 U.S. at 415, 93 S.Ct. 2507. Likewise, the presence of a "dominant federal interest" offers little insight since "every subject that merits congressional legislation is, by definition, a subject of national concern." *Hillsborough Cnty.*, 471 U.S. at 719, 105 S.Ct. 2371. Yet it cannot follow "that every federal statute ousts all related state law." *Id.*

Since "pervasive regulation" and the presence of a "dominant federal interest" alone do not provide clear evidence of congressional intent, we must look to other "special features warranting pre-emption" of the field. *Id.* The Supreme Court's cases reveal two "special features" that warrant finding preemption of a narrow zone within a traditional state field like health and safety. The first is when preemption of the limited zone is the "natural implication of [the statutory] provision." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 100, 112 S.Ct. 2374, 120 L.Ed.2d 73 (1992) (finding Congress preempted the field of training standards for workers handling hazardous waste). For example, the Supreme Court found that a statute federalized the area of tobacco classification and inspection when the text emphasized the importance of "uniform standards." *Campbell v. Hussey*, 368 U.S. 297, 301–02, 82 S.Ct. 327, 7 L.Ed.2d 299 (1961).

The other "special feature" arises when the statute addresses an area historically reserved to the federal government. One such area is interstate navigation, where federal dominance "has been manifest since the beginning of our Republic." *United States v. Locke*, 529 U.S. 89, 99, 120 S.Ct. 1135, 146 L.Ed.2d 69 (2000) (oil tankers); *see also City of Burbank v. Lockheed Air Terminal Inc.*, 411 U.S. 624, 625, 93 S.Ct. 1854, 36 L.Ed.2d 547 (1973) (aircraft). Another is nuclear safety, a field Congress has monopolized since the inception of nuclear power. *English v. Gen. Elec. Co.*, 496 U.S. 72, 80–81, 110 S.Ct. 2270, 110 L.Ed.2d 65 (1990).

***8** Neither of those two special features are present here. For starters, the text of the FDAAA suggests that Congress intended to create a regulatory floor, not a ceiling. The states are not free to dilute congressional safety measures, but they are free to strengthen them. Congress and the Supreme Court have said as much. When Congress amended the FDCA in 1976 to regulate medical devices, it chose to include a provision expressly preempting state laws in the field. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539, 574, 21 U.S.C. § 360k(a). But when it passed the FDAAA in 2007, "it declined to enact such a provision for prescription drugs." *Wyeth v. Levine*, 555 U.S. 555, 567, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009). The "natural implication" is that Congress knows how to preempt state public health laws when it wants to, and it did not do so in the FDAAA. As the Supreme Court has made quite plain, "Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008).

To the extent Congress has spoken on preemption in the area of prescription drugs, it has chosen to allow state regulation. The 1962 amendments to the FDCA included a saving clause indicating that state drug regulations were only preempted if there was a "direct and positive conflict" with the statute. Drug Amendments Act of 1962, Pub. L. No. 87-781, 76 Stat. 780, 793. While this saving clause cannot directly control the preemptive effect of the later-enacted FDAAA, it does provide "powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Wyeth*, 555 U.S. at 575, 129 S.Ct. 1187.

The very presence of the saving clause indicates that Congress has chosen to tread carefully and incrementally in the field of drug regulation. GenBioPro, however, urges upon us the very opposite, namely an exclusive federal power that preempts the ability of the states to protect the well-being of their very own citizens. Congress's approach and GenBioPro's approach could not be further or more diametrically apart.

Nor does the FDAAA address a subject historically reserved to the federal government. As for drugs subject to safe-use elements, the brief period of FDA regulation in this area falls well short of a longstanding federal monopoly. And as for prescription drugs more generally, the 1962 saving clause underscores the tradition of shared authority between the federal government and the states. Indeed, the states have a "long history" of regulating drugs, and they have continued to play a significant role since the emergence of federal oversight. Patricia J. Zettler, *Pharmaceutical Federalism*, 92 IND. L.J. 845, 852–61 (2017). For instance, the states have maintained "their own Food, Drug, and Cosmetic Acts" and "tort law schemes" complementing the FDA's regulation of prescription drugs. *Id.* at 859–60. This history suggests a complementary exercise of federal and state power when it comes to the safe utilization of high-risk drugs, not a one-sided ouster of state efforts in this area.

B.

We last address GenBioPro's contention that the West Virginia law conflicts with the FDAAA. There are two types of conflict preemption. The first arises when "it is impossible for a private party to comply with both state and federal requirements." *English*, 496 U.S. at 79, 110 S.Ct. 2270. The second occurs when "state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' " *Id.* (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67, 61 S.Ct. 399, 85 L.Ed. 581 (1941)).

GenBioPro argues that both forms of conflict preemption apply here. The company claims that it cannot comply with both federal and state law because the FDA has authorized the sale of mifepristone while the state has banned its use. It likewise argues that the West Virginia law poses an obstacle to the FDAAA's goal of ensuring drug access. In its view, Congress struck a careful balance between drug safety and access, and West Virginia's abortion law disrupts this balance by burdening access to mifepristone.

***9** Both of these theories rely on the same flawed premise: that Congress intended to guarantee nationwide access to mifepristone when it enacted the FDAAA. We see no indication that it did. The FDAAA authorized the FDA to establish minimum safety rules for administering

drugs like mifepristone where they may be legally prescribed. It did not create a right to utilize any particular high-risk drug, which would have constituted a significant intrusion into a state's traditional authority to protect the health and welfare of its citizens.

The text reveals this focus on safety. The preamble provides that Congress enacted the FDAAA "to enhance the postmarket authorities of the Food and Drug Administration with respect to the safety of drugs." Pub. L. 110-85, 121 Stat. 823, 823. The Act accomplishes this goal by directing the FDA to require compliance with a REMS whenever one is "necessary to ensure that the benefits of the drug outweigh the risks." 21 U.S.C. § 355-1(a)(1). It then spells out that a REMS can include various restrictions "necessary to assure safe use of the drug," such as requiring providers and pharmacies to obtain special certifications, limiting distribution to particular health care settings, or mandating that patients undergo certain testing before receiving the drug. *Id.* § 355-1(f).

Notwithstanding this emphasis on safety, GenBioPro insists that the statute was also intended to protect *access* to REMS drugs. In support of this claim, GenBioPro points to various mentions of "drug access" scattered throughout the statute. For instance, the title of the section authorizing safe-use elements is "Providing Safe Access for Patients to Drugs with Known Serious Risks that Would Otherwise Be Unavailable." *Id.* In a subsection titled "Assuring Access and Minimizing Burden," the statute establishes that the FDA's safe-use elements cannot be "unduly burdensome on patient access to the drug" and should "minimize the burden on the health care delivery system." *Id.* § 355-1(f)(2). A few subsections later, the Act directs the FDA to periodically evaluate its restrictions to determine whether they unduly burden patient access or the health care delivery system. *Id.* § 355-1(f)(5). In GenBioPro's view, these provisions demonstrate that Congress struck a balance that authorized additional safety measures while also guaranteeing access to the covered drugs.

This interpretation fundamentally misunderstands the FDA's mission. The agency's task has always been to "ensure[ ] that drugs on the market are safe and effective." *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 374–75, 144 S.Ct. 1540, 219 L.Ed.2d 121 (2024). It has never been authorized to "regulate the practice of medicine" or mandate that specific drugs be available. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 351, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001). To read an access mandate into the FDAAA would be to radically redefine the FDA's historic role and authorize an unprecedented federal intrusion into the regulation of medical practice—an area long reserved to the states. *See Gonzales v. Oregon*, 546 U.S. 243, 275, 126 S.Ct. 904, 163 L.Ed.2d 748 (2006). To the extent that the statute directs the FDA to avoid burdening access to drugs, that directive aligns with its traditional function of ensuring the safety of drugs on the market while leaving the question of access to state governance.

It is also worth pausing to reflect on the sheer breadth of GenBioPro's position. The FDA has imposed a REMS on a wide array of potent drugs, including highly dangerous opioids such as fentanyl. *See, e.g.*, U.S. Food & Drug Admin., Transmucosal Immediate Release Fentanyl (TIRF) Shared System REMS Program (2024). Under GenBioPro's interpretation, the FDAAA would preempt any state law restricting access to those drugs. State governments would be powerless, for example, to limit prescriptions of addictive opioids or even enforce their bans on physician-assisted suicide against doctors seeking to prescribe lethal drugs regulated under a REMS. And according to GenBioPro, Congress brought about this dramatic result by alluding to "drug access" in the title of a subsection and instructing the FDA to ensure that *its own* restrictions do not unduly burden access.

***10** We think Congress would have spoken with a much clearer voice if it intended to effect such a radical change in the federal-state balance. In our view, the statute means exactly what it says—the FDA can impose safe-use restrictions on high-risk drugs, and *those restrictions* cannot unduly burden access to the drug. But that does not cut the states out of the picture. We do not dispute that, as it does with all laws, Congress sought to "strike a balance" between competing interests when it enacted the FDAAA. *Chamber of Com. v. Whiting*, 563 U.S. 582, 606, 131 S.Ct. 1968, 179 L.Ed.2d 1031 (2011). But courts are confined to enforcing the balance that is reflected in the text of the statute. We are not permitted to undertake a "freewheeling judicial inquiry" into an alternative balance that Congress may have hidden between the lines. *Id.* at 607, 131 S.Ct. 1968 (quoting *Gade*, 505 U.S. at 111, 112 S.Ct. 2374 (Kennedy, J., concurring in part and concurring in the judgment)). The text here limits the FDA but not the states from restricting access to REMS drugs. We are therefore left with the unmistakable conclusion that "[p]art of that balance" Congress struck "involved allocating authority between the Federal Government and the States." *Id.* at 606–07, 131 S.Ct. 1968.

We respect the fact that appellant and some amici have argued that access to mifepristone is important to the health of women in the course of their reproductive

choices. *See, e.g.*, Brief of Amicus Curiae Doctors for America; Brief of Amicus Curiae American College of Obstetricians & Gynecologists. Our objection is not to the substance of this point, but to the venue in which it is advanced. It is exactly the sort of policy argument that the Supreme Court anticipated would be significant in the legislative deliberations of the various states. The corollary of this is that the debate joined by able and dedicated supporters and opponents of access to abortion medications is simply not one, in the absence of clear congressional direction, for this court to decide.

A large part of our dissenting friend's opinion is devoted to the abovementioned amicus briefs. The amicus briefs make for thoughtful reading, and we are fortunate to have them. At the same time, they resemble an engraved invitation to this court to assume a legislative role. Policy upon policy is paraded by the dissent as to why the West Virginia law is ill-advised. But again, we simply lack authority as a federal court to substitute our policy preferences for those of the West Virginia legislature. Litigation was never meant to displace the hard democratic work of persuading the people's representatives. The arguments must be matched to the forum, and the mismatch is glaring in this case.

V.

Just after the Supreme Court restored the states' traditional authority to regulate abortion, GenBioPro would have us wrest it right back from them. Appellant attempts to assemble a preemption theory out of statutory scraps and fragments that do nothing to hide the fact that the theory is but a fig leaf for an assault on the *Dobbs* decision. We are asked to infer sweeping field preemption over a broad swath of high-risk drugs in the face of a saving clause indicating that Congress chose nothing of the sort. We are further asked to prevent the states from protecting the health and safety of their citizens whenever their laws touch upon high-risk drugs in any way. Not only that, but we are asked to do all this under what are at best the fuzziest set of federal instructions when the Supreme Court has insisted upon congressional clarity. If Congress wishes to preempt laws like West Virginia's, why hasn't it come right out and said so? For us to sally forth and strike down this statute in the face of all these obstacles invites certain reversal. "Into the valley of Death Rode the six hundred." Alfred Lord Tennyson, *The Charge of the Light Brigade* (1854).

Our decision, by contrast, is a narrow one. We take no position on the wisdom or folly of West Virginia's abortion law. As *Dobbs* makes clear, that judgment belongs with the people and their elected representatives. One can of course agree or disagree with the *Dobbs* decision. But that is not the point. At a time when the rule of law is under blunt assault, disregarding the Supreme Court is not an option. We do not suggest that the FDAAA lacks any preemptive effect. States are certainly not free to dilute federal safety standards where they have been clearly established. Nor do we deny that Congress may preempt state abortion laws if it chooses to do so and acts pursuant to its enumerated powers. We simply hold that it must express that intention with the clarity befitting such a significant alteration to our system of dual sovereignty. Because the FDAAA does not do so, we decline to overturn the West Virginia law.

***11** The judgment of the district court is accordingly affirmed.

AFFIRMED

DeANDREA GIST BENJAMIN, Circuit Judge, concurring in part and dissenting in part:

In a troubling opinion, the majority finds that a West Virginia law, which is a near outright ban on access to mifepristone, is not preempted by federal regulations. Put plainly, this law erects barriers to life-saving healthcare for countless West Virginians in ways not envisioned by Congress. Despite the law's overbreadth and potentially fatal consequences—to say nothing of its dangerous spillover effects on healthcare systems serving vulnerable communities in neighboring states—the majority would allow West Virginia's Unborn Child Protection Act ("UCPA") to stand.

But the twin sensitivities of abortion access and states' rights cannot influence our willingness to recognize the Food and Drug Administration's (FDA) clear authority in this area. And they cannot justify inaction as West Virginia enacts legislation which upsets "the constitutional balance between the National Government and the States." *See* Maj. Op. at —— (quoting *Bond v. United States*, 572 U.S. 844, 857, 134 S.Ct. 2077, 189 L.Ed.2d 1 (2014)). So, while I concur in the majority's finding that GenBioPro has standing to sue, because the UCPA is preempted by federal law, I must respectfully dissent.

In the majority's view, neither field preemption nor conflict preemption thwarts West Virginia's passage of the UCPA. I address and reject each point in turn.

I.

A.

In 2011, the FDA approved a REMS for mifepristone, allowing mifepristone to be "prescribed by certified physicians up to 49 days of pregnancy, dispensed in certain healthcare facilities, and taken in the provider's clinic." *GenBioPro, Inc. v. Sorsaia*, No. 3:23-0058, 2023 WL 5490179, at *2 (S.D.W. Va. Aug. 24, 2023). In 2016, the FDA revised the REMS for mifepristone, "increasing the gestational age through which the drug is indicated, expanding those who could be certified to prescribe mifepristone from 'physicians' to 'healthcare providers,' and reducing the number of required patient visits to their healthcare providers." *Id.* And in 2023, "the FDA promulgated a new REMS for mifepristone," which for the first time "allow[ed] patients to receive the medication either by mail or from certified pharmacies" without "in-person visits to healthcare providers." *See id.*; U.S. Food & Drug Admin., Risk Evaluation and Mitigation Strategy (REMS): Single Shared System for Mifepristone 200 mg (2023) (hereinafter "2023 REMS"), https://perma.cc/4K97-EAWA.

As acknowledged by the majority, the safe use elements require that dispensing pharmacies and prescribing providers be certified. *See* 2023 REMS at 9–15. Certified providers must be able to "assess the duration of pregnancy accurately," "diagnose ectopic pregnancies," and "provide surgical intervention in cases of incomplete abortion or severe bleeding, or [ ] have made plans to provide such care through others, and [have the] ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary." *Id.* at 1. Certified providers must, among other things, provide relevant forms and information to the patient regarding the treatment regimen and risks associated with mifepristone. *See id.* at 1–4.

***12** Dispensing pharmacies are also subject to extensive requirements for certification, including shipping the mifepristone within four calendar days of receiving the prescription, tracking and verifying such shipments, maintaining detailed records, and reporting any patient deaths. *See id.* at 3.

B.

By comparison, the UCPA seeks to outlaw performing, inducing, or attempting to perform or induce an abortion, including medication abortions, with limited exceptions. *See* W. Va. Code § 16-2R-2, 3. The UCPA provides exceptions when "in the reasonable medical judgment of a licensed medical professional: (1) [t]he embryo or fetus is nonviable; (2) [t]he pregnancy is ectopic; or (3) [a] medical emergency exists." W. Va. Code § 16-2R-3(a). A competent adult may seek an abortion within the first eight weeks of pregnancy if their pregnancy is the result of sexual assault or incest and the patient reported the assault or incest to law enforcement at least 48 hours before the abortion. *See* W. Va. Code § 16-2R-3(b). The UCPA similarly creates an exception for minors and incompetent or incapacitated adults within the first 14 weeks if the pregnancy is the result of sexual assault or incest and if, at least 48 hours before the abortion, the patient reported the assault or incest to law enforcement or "received medical treatment for the same." W. Va. Code § 16-2R-3(c).

A licensed and formerly-licensed medical professional who performs or attempts to perform an abortion in violation of the statute is subject to disciplinary action by their licensing board and criminal prosecution. W. Va. Code § 16-2R-7, 8(a), 8(b), 61-2-8. Penalties include, but are not limited to, loss of licensure and up to 10 years in prison. W. Va. Code §§ 16-2R-7, 61-2-8.

II.

Under the field preemption theory, the majority contends that the UCPA and the Food and Drug Administration Amendments Act ("FDAAA") "operate in different fields." Maj. Op. at ——. The FDAAA includes (1) risk evaluation and mitigation strategies ("REMS") and (2) elements to assure safe use ("safe use elements"). This comprehensive framework for accessing drugs thereby precludes state regulations governing the same. I therefore disagree with the majority's conclusion.

A.

Field preemption occurs when "Congress occupies a certain field by 'regulating so pervasively that there is no room left for the states to supplement federal law' " or when "there is a 'federal interest ... so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.' " *United States v. South Carolina*, 720 F.3d 518, 528–29 (4th Cir. 2013) (first quoting *Cox v. Shalala*, 112 F.3d 151, 154 (4th Cir. 1997); and then quoting *Arizona v. United States*, 567 U.S. 387, 399, 132 S.Ct. 2492, 183 L.Ed.2d 351 (2012)). When Congress intends " 'to foreclose any state regulation in [an] *area*,' irrespective of whether state law is consistent or inconsistent with 'federal standards[,]' ... Congress has forbidden the State to take action in the *field* that the federal statute pre-empts." *Oneok Inc. v. Learjet, Inc.*, 575 U.S. 373, 377, 135 S.Ct. 1591, 191 L.Ed.2d 511 (2015) (quoting *Arizona*, 567 U.S. at 401, 132 S.Ct. 2492).

The underlying principles of preemption are governed by the Supremacy Clause, which "provides that 'the Laws of the United States' (as well as treaties and the Constitution itself) 'shall be the supreme Law of the Land[,] ... any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.' " *Oneok*, 575 U.S. at 376, 135 S.Ct. 1591 (quoting U.S. Const. art. VI, cl. 2).

B.

***13** West Virginia's extensive limitations on access to abortion care, which near an outright ban, can hardly be said to be "complementary" or "incidental" to the FDA's regulations, as the majority argues. *See* Maj. Op. at ——, ——. Quite the contrary. The limitations set forth by the FDA are, as GenBioPro argues, pervasive. Appellant's Br. (ECF No. 31) at 26 (hereinafter "Opening Br."). The UCPA regulates, in large part, access to the medication that facilitates an abortion and criminalizes licensed medical professionals for providing abortion care in violation of the statute. The FDA's REMS and safe use elements for mifepristone regulate the information provided to patients, the certification requirements of pharmacies and medical providers, and the time limits within which mifepristone may be prescribed and must be provided, among other requirements. *See* 2023 REMS at 1–2, 4. The UCPA particularly encroaches on the federal government's regulatory authority by criminalizing medical professionals for prescribing a medication that they are otherwise federally certified to prescribe. In doing so, the UCPA ventures far beyond "tangentially touching the federal domain," as the majority claims. *See* Maj. Op. at ——. It invades the very space occupied by the federal government and reserved for federal oversight—the regulation of medication.

Both the FDA and West Virginia, then, substantially regulate mifepristone. Where Congress has carefully crafted its own comprehensive and thoughtful regulatory scheme to ensure safe access to a drug, and a state statute undermines those federal regulations, the state oversteps. This is so even in light of *Dobbs v. Jackson Women's Health Org.*, which left the issue of abortion with the states. 597 U.S. 215, 292, 142 S.Ct. 2228, 213 L.Ed.2d 545 (2022). The majority in part relies on the appendices in *Dobbs*, which list the various state statutes in history that have criminalized abortion including through medicine and drugs, dating as far back as 1825 and as recently as 1952. *See* Maj. Op. at —— – ——; *Dobbs*, 597 U.S. at 302–330, 142 S.Ct. 2228. This plainly ignores that the FDA has since *approved* medications used for abortion and has continued to revise the REMS, including as recently as 2023, to make the medication *more accessible* to patients. *See GenBioPro, Inc.*, 2023 WL 5490179, at *2 (explaining that the 2023 REMS for the first time allowed patients to receive mifepristone "either by mail or from certified pharmacies" without "in-person visits to healthcare providers."); 2023 REMS. By criminalizing medical providers and prohibiting medication abortions, then, West Virginia has exceeded the ability to regulate abortion as established in *Dobbs* and has trespassed on the FDA's authority to regulate the safe use of and unburdened access to mifepristone. Stated simply, the majority's conclusion on this point focuses on regulation of abortion generally, despite the issue here being the state regulation of an otherwise federally approved drug—a much narrower focus. The federal government has clearly occupied the drugs with REMS and elements to assure safe use field, and West Virginia overreaches by seeking to add additional regulations to the same. Accordingly, field preemption applies.

C.

The majority admits that field preemption may occur in a "narrow zone within a traditional state field like health and safety." Maj. Op. at ——. But the majority stumbles on this point. As an example of a narrow subset subject to field preemption, the majority points to tobacco product regulations. The majority highlights that "the Supreme Court found that a statute federalized the area of tobacco classification and inspection when the text emphasized the importance of 'uniform standards.' " *Id.* at —— (citing *Campbell v. Hussey*, 368 U.S. 297, 301–02, 82 S.Ct. 327, 7 L.Ed.2d 299 (1961)). The majority then claims the situation here is different. It is not.

In *Campbell*, the Supreme Court found that there could only be "but one 'official' standard" for tobacco labeling—"one that is 'uniform' and that eliminates all confusion by classifying tobacco not by geographical origin but by its characteristics." 368 U.S. at 301, 82 S.Ct. 327. In doing so, the Court relied on language in the Federal Tobacco Inspection Act that emphasized the need for uniformity. *Id.*

Here, the same principles apply. The FDA regulation for drugs requiring REMS provides that the safe use elements should—"to the extent practicable, so as to minimize the burden on the health care delivery system—*conform with elements to assure safe use for other drugs with similar, serious risks*; and be designed to be compatible with established distribution, procurement, and dispensing systems for drugs." 21 U.S.C. § 355-1(f)(2)(C), (D) (emphasis added). This indicates an intent by the FDA to regulate drugs with similar risks uniformly. To be clear, only 325 REMS have ever been approved.[1] And only 77 REMS are currently active.[2] Given the more than 34,000 drugs the FDA has approved to date, *see* Hao Zhong et al., *A Comprehensive Map of FDA-Approved Pharmaceutical Products*, 10 Pharmaceutics 263 (2018), and the more than 10,000 FDA-approved drugs in circulation, *see* Barbara J. Evans, *Seven Pillars of A New Evidentiary Paradigm: The Food, Drug, and Cosmetic Act Enters the Genomic Era*, 85 Notre Dame L. Rev. 419, 428 (2010), the less than one percent of drugs subject to REMS is, by definition, a narrow zone.

1 *See* FDA Risk Evaluation and Mitigation Strategy (REMS) Public Dashboard, https://fis.fda.gov/sense/app/ca606d81-3f9b-4480-9e47-8a8649da6470/sheet/6840df68-c772-45f1-bc4f-39d8b04cbfc1/state/analysis [https://perma.cc/88RD-7WAP].

2 *Id.*

***14** Because the FDA has indicated the need for uniform regulations, and those regulations are comprehensive, field preemption clearly applies. For the reasons explained below, the UCPA is also preempted by conflict preemption.

III.

The majority also concludes that conflict preemption does not apply, finding that the FDA does not mandate access to a drug and only serves to regulate the safety and effectiveness of a drug. Because the UCPA burdens patients and healthcare systems and imposes inconsistent regulation of mifepristone in ways not intended by Congress, conflict preemption also precludes the state law.

A.

Conflict preemption occurs when "state law is preempted 'to the extent it actually conflicts with federal law[.]' " *South Carolina*, 720 F.3d at 529 (quoting *Cox*, 112 F.3d at 154). This type of preemption "includes cases where compliance with both federal and state regulations is a physical impossibility, and those instances where the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* (quoting *Arizona*, 567 U.S. at 399, 132 S.Ct. 2492). This court has explained that conflict preemption can be separated into two categories: (1) direct conflict preemption, when compliance with both regulations is a "physical impossibility"; and (2) obstacle preemption, when the state law at issue is "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress[.]" *Guthrie v. PHH Mortg. Corp.*, 79 F.4th 328, 336–37 (4th Cir. 2023) (quoting *S. Blasting Servs., Inc. v. Wilkes Cnty.*, 288 F.3d 584, 590 (4th Cir. 2002)).

The FDA is tasked with "ensur[ing] that drugs on the market are safe and effective." *Food and Drug Admin. v.*

All. for Hippocratic Med., 602 U.S. 367, 374–75, 144 S.Ct. 1540, 219 L.Ed.2d 121 (2024); *see also* 21 U.S.C. § 393 (providing that the FDA is responsible for "promot[ing] the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner" including "protect[ing] the public health by ensuring that ... drugs are safe and effective"). "If FDA determines that additional safety requirements are necessary, FDA may impose extra requirements on prescription and use of the drug." *All. for Hippocratic Med.*, 602 U.S. at 375, 144 S.Ct. 1540 (citing 21 U.S.C. § 355-1(f)(3)). Among the risk evaluation and mitigation strategies considered and imposed by the FDA are those that "provid[e] safe access for patients to drugs with known serious risks that would otherwise be unavailable," including "minimiz[ing] the burden on the health care delivery system." 21 U.S.A. § 355-1(f)(2)(D).

B.

Obstacle preemption arises here. The UCPA frustrates the FDA's purpose—to assure the public's safe use of drugs and to minimize any attendant burdens on patient and healthcare systems. The FDA regulation for drugs requiring REMS and safe use elements provides that the "elements to assure safe use" of drugs "with known serious risk" as delineated in 21 U.S.C. § 355-1(f)(1) shall "not be unduly burdensome on patient access to the drug[,]" particularly considering patients with serious conditions, those who have trouble accessing healthcare, and those with functional limitations. 21 U.S.C. § 355-1 (f)(2)(C), (D). The statute further provides that the safe use elements should—"to the extent practicable, so as to minimize the burden on the health care delivery system—conform with elements to assure safe use for other drugs with similar, serious risks; and be designed to be compatible with established distribution, procurement, and dispensing systems for drugs." *Id.*

***15** The majority contends that the language of the statute clearly limits the burdens the FDA imposes on itself with its safe-use restrictions. *See* Maj. Op. at ——. This ignores an alternate, and plausible reading: that the language indicates an intention to minimize external burdens. *See id.* The statute's emphasis on ensuring the safe use elements applicable to similar drugs are uniformly applied highlights this point.

The UCPA, frustrates this purpose by adding additional burdens to the access of mifepristone by, for example, significantly limiting the circumstances in which a patient may be eligible to receive the drug, requiring reports to law enforcement in cases of incest and rape before an individual can use the drug, and penalizing licensed medical professionals for providing abortion care outside of the other limited circumstances provided by the UCPA: non-viable pregnancies, ectopic pregnancies, or medical emergencies.

The majority also contends that the saving clause included in the 1962 amendments to the Federal Food, Drug, and Cosmetic Act ("FDCA") provides "powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness."[3] Maj. Op. at —— – —— (quoting *Wyeth v. Levine*, 555 U.S. 555, 575, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009)). Even if the 1962 amendments did include a saving clause, however, "neither an express pre-emption provision nor a saving clause 'bar[s] the ordinary working of conflict pre-emption principles.' " *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001) (quoting *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000)). This conclusion, therefore, also fails.

[3] The saving clause included in the 1962 FDCA amendment reads "Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law." FDCA, § 202, 76 Stat. 781, 793, as amended, 21 U.S.C. § 301 *et seq.*

C.

Multiple amici have aptly highlighted the ways state laws like the UCPA inhibit the FDAAA's goal of providing uniform access to drugs like mifepristone. For example, the Economists describe that "abortion clinic closures increase the distances patients must travel to obtain care," thereby requiring a West Virginia resident to "travel an average of 108 miles to the nearest abortion provider in a neighboring state, an increase of 62 miles from prior to the enactment of the UCPA." Br. for Economists as

Amici Curiae Supporting Appellant (ECF No. 34) at 10, 13.[4] Although the safe use elements require specific consideration of the burdens placed on "patients who have difficulty accessing health care (such as patients in rural or medically underserved areas)," "three-quarters of abortion seekers are poor or low-income," and are thus some of the most impacted. 21 U.S.C. § 355-1(f)(2)(C)(ii); Br. for Economists at 23–24.[5] "Abortion restrictions also have greater impacts on other populations that have difficulty accessing health care, such as adolescent women and women of color."[6] Br. for Economists at 25.

4 *See* Br. for Economists at 10, 13 (citing Caitlin Myers, *Forecasts for a Post-Roe America: The Effects of Increased Travel Distance on Abortions and Births*, 43 Journal of Policy Analysis and Management).

5 *See* Br. for Economists at 23–24 (citing Jenna Jerman et al., *Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2009*, New York: Guttmacher Institute, (May 2016), https://perma.cc/92B2-SXNT).

6 The Economists' position is firmly grounded in science. In support of these contentions, the Economists cite more than a dozen empirical studies based on data from across the country. *See generally* Jason Lindo and Mayra Pineda-Torres, *New Evidence on the Effects of Mandatory Waiting Periods for Abortion*, 80 Journal of Health Economics at 102533 (2021); Caitlin Myers, *Cooling Off or Burdened? The Effects of Mandatory Waiting Periods on Abortions and Births*, IZA Discussion Paper No. 14434 (2021); Jones, Kelly M. et al., *TRAP'd Teens: Impacts of Abortion Provider Regulations on Fertility & Education*, IZA Discussion Paper No. 14837 (2021); Caitlin Myers, *Forecasts for a Post-Roe America: The Effects of Increased Travel Distance on Abortions and Births*, 43 No. 1 Journal of Policy Analysis and Management (2024).

***16** Further, and unsurprisingly, "an abortion restriction in one geographic area leads to increased clinic congestion in neighboring areas without abortion restrictions." *Id.* at 11, 26–27 (collecting sources noting the impacts of clinic closures due to similar laws in Texas and Pennsylvania). That "[i]ncreased clinic congestion also impedes access by leading to delays in abortion timing, reduction in abortions, and an increase in births"—and not just for citizens of the state which enacted the restrictive legislation. *See id.* at 11, 28–30 (collecting sources noting the impacts of abortion restrictions on neighboring states). The burdens placed on neighboring states could easily be mitigated by medication abortion (i.e., access to mifepristone), which account for over half of abortions in the United States. *See id.* at 31.[7]

7 *See* Br. for Economists at 31 (citing Rachel Jones et al., *Medication Abortion Now Accounts for More than Half of All US Abortions*, Guttmacher Institute, Feb. 2022, https://perma.cc/7YBZ-VS83).

The restrictions on this access imposed by the UCPA have material impacts on West Virginia's neighboring states. The City of Baltimore notes that West Virginians who are unable to access abortion care often travel to Maryland and that "West Virginia's deauthorization of mifepristone burdens underserved patients and regional health care delivery systems." Br. for City of Baltimore as Amici Curiae Supporting Appellant (ECF No. 38) at 1–2, 8, 10–11. The City highlights that "[n]early all of West Virginia's counties contain a federally designated medically underserved area or population, while more than 75% of Baltimore residents (and over a million Marylanders statewide) similarly reside in medically underserved areas." *Id.* at 9[8].

8 *See* Br. for City of Baltimore at 9 (first citing U.S. Department of Health and Human Services, *Medically Underserved Area and Medically Underserved Population Designations Throughout the United States*, https://data.hrsa.gov/tools/shortage-area/mua-find; and then citing Maryland Department of Health, 2021 Primary Care Needs Assessment (Sept. 20, 2021), https://perma.cc/3KZG-UYCD).

Baltimore residents seeking general medical care face several weeks' wait times "even without the increased demand from out-of-staters seeking appointments and care." *Id.*[9] In the first quarter of 2023 alone, an estimated 3,980 people traveled to Maryland for abortion care. *Id.* at 10.[10] This increased strain placed on Maryland's healthcare systems has "exact[ed] enormous costs on [Maryland's] providers, residents, and support networks," including requiring clinic staff to work overtime and burdening other support systems with "hugely increased call volumes, and far more financial requests for travel, child care, and other logistical supports." *Id.* at 11.[11]

9 *See* Br. for City of Baltimore at 9 (citing Milbank Memorial Fund, *Assessing the Effectiveness of Policies to Improve Access to Primary Care for Underserved Populations: A Case Study Analysis of Baltimore City, Maryland* (Aug. 12, 2022), https://perma.cc/QYF2-TUNN).

[10] *See* Br. for City of Baltimore at 10 (citing Guttmacher Institute, *Monthly Abortion Provision Study*, https://perma.cc/G7TU-EJDE).

[11] *See* Br. for City of Baltimore at 11 (first citing Amy Zimmardi, *Maryland Becomes Haven for Out-of-State Abortion Seekers, Providers*, Capital News Service (Sept. 15, 2022), https://perma.cc/6HR4-H3FL; and then citing Eden Stiffman, *Abortion Funds Face Slowdown in Giving a Year after Supreme Court Ruling*, The Chronicle of Philanthropy, June 12, 2023, https://www.philanthropy.com/article/abortion-funds-face-slowdown-in-giving-a-year-after-supreme-court-ruling [https://perma.cc/LD8S-S32U]).

The UCPA therefore has a tangible and material impact on the healthcare systems in other states. Access to abortion care for both West Virginians and residents of neighboring states, like Maryland, is harmed by longer wait times based on the influx of West Virginians into those states. These burdens are contrary to the requirement that the safe use elements not be "unduly burdensome on patient access" or on the health care delivery system. 21 U.S.C. § 355-1(f)(2)(C), (D).

***17** Doctors for America advises that state regulations like the UCPA can undermine uniform medical education and prevent medical students from being taught about relevant medication based on the laws in the state in which they are educated. Br. for Doctors for America as Amici Curiae Supporting Appellant (ECF No. 33) at 31–32. The Accreditation Council for Graduate Medical Education ("ACGME"), which "sets standards for U.S. graduate medical education programs and the institutions that sponsor them," requires obstetrics and gynecology residency programs "to provide abortion training, or else risk losing their accreditation." *Id.* at 31. This requirement, in light of the UCPA, requires medical-training programs to "fac[e] a treacherous choice: continue to provide abortion training in States where the procedure is now outlawed and face prosecution, or else risk losing their accreditation, which in turn would render their residents ineligible to receive specialty board certification and imperil recruitment of faculty and medical students." *Id.* at 31–32. When laws like the UCPA ban access to "critical" abortion medications, "medical schools in those States may not be able to educate their students to the national standard, and physicians earning their degrees from these schools may be unprepared to practice in other parts of the country." *Id.* at 31.

The UCPA's potential impact on medical education again places additional burdens on both patient access and the health care delivery system, as the ban may well limit the number of medical professionals who are trained to prescribe mifepristone. This harm ventures beyond the borders of West Virginia and may have widespread effects on patient access and the health care system, contrary to the intentions set forth in the safe use elements. *See* 21 U.S.C. § 355-1(f)(2)(C), (D).

Finally, because pregnancy can be a serious or life-threatening condition, mifepristone "is an important tool" for clinicians who treat pregnant patients and "[t]he medical evidence ... amply justifies the FDA's decisions to approve mifepristone and to reduce restrictions on access to mifepristone." Br. of Am. Coll. of Obstetricians and Gynecologists et al. as Amici Curiae Supporting Appellant (ECF No. 44) at 31. The American College of Obstetricians and Gynecologists cautions:

> The potential risks posed by pregnancy are far greater for persons of color, low-income persons, and those living in rural areas. Low-income patients and patients of color are most likely to experience severe maternal morbidity and more likely to die from pregnancy-related complications, and those in rural areas are disproportionately harmed by restrictions on abortion care.

Id. at 30–31 (collecting sources).

"[T]he FDA is required to consider the burden on 'patients with serious or life-threatening diseases or conditions,'" *id.* at 23, and so these are relevant factors the FDA "is required to consider in determining the appropriate restrictions on mifepristone." *See id.* at 30 n.47 (citing 21 U.S.C. § 355-1(f)(2)(C)(ii)). These significant burdens on both patients and the healthcare system are precisely those the FDA sought to avoid. *See* 21 U.S.C. § 355-1(f)(2)(C)(ii) (limitations must be designed to "not be unduly burdensome on patient access to the drug, considering in particular ... patients who have difficulty accessing health care (such as patients in rural or medically underserved areas)").

The consequences of the UCPA, as thoughtfully explained by these amicus briefs, are not mere policy preferences as the majority suggests. *See* Maj. Op. at ——– ——. These are severe repercussions that encroach upon the regulatory scheme set forth by the FDA in ways the FDA specifically sought to avoid. To suggest that the FDA would specify an interest in minimizing burdens while simultaneously allowing states to impose their own highly variable burdens defies all logic. For these reasons, the UCPA, which serves as a near-outright ban and imposes substantial burdens on patients and the healthcare

system alike, is barred by obstacle preemption.

IV.

Although the basis for each preemption theory differs, the UCPA is preempted by both field and obstacle preemption. The comprehensive nature of the REMS for the narrow list of drugs it governs occupies the field such that there is no room for additional restrictions by the UCPA. And the FDA's explicit intention to minimize the burdens to patients and healthcare systems is incompatible with the burdens placed on both by the UCPA. As such our directive here is clear: allow the regulation of drugs with REMS to remain where it belongs—with the federal government.

All Citations

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